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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,878	01/25/2002	Gordhanbhai N. Patel	PATL 3. 0-012/PCT/US	1198
7590	12/19/2003			
Joseph T. Guy, Ph.D. Nexsen Pruet Jacobs & Pollard LLC 201 West McBee Avenue Suite 400 Greenville, SC 29601				
			EXAMINER	
			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/031,878

Applicant(s)

PATEL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 40-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: Pages 21 and 24 are not numbered. Appropriate correction is required. Applicants' preliminary amendment to the claims has been entered. Accordingly, claims 12-39 and 49 have been cancelled. Claims 1-11 and 40-48 are pending.

### *Priority*

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

### *Claim Observations*

- Claim 9 mentions the term "styrene" twice.
- There is no antecedent basis for "the anion" in claims 43, 45 and 48.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1-5, 9, 10 and 40, 41, 43 and 45, 46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,451,372 to Larsson et al.

Larsson et al teach a device for monitoring sterilization process using ethylene oxide. The device comprises an ethylene responsive chemical, a quantifier and a pH sensitive dye. The pH indicator is responsive to change in pH. Larsson et al teach bromophenol blue and thymol blue, as recited in claim 4 (col. 3, lines 34-42). The ethylene responsive chemical is equivalent to Applicants' claimed activator. Larsson et al teach compounds containing a monovalent cation and monovalent anion. Specific examples include alkaline earth metal salts, where the anion may be a halide as recited in claims 43 and 45 (col. 3, lines 13-22). As a polymeric carrier, Larsson et al teach using acrylic acid polymers, as recited in claims 9 and 10 (col. 4, lines 34-48). With respect to method claims 40, 40, 41 and 46, Larsson et al teach preparing a device comprising a pH indicator, ethylene responsive chemical prepared with an acrylic acid polymer, subjecting the device to an ethylene oxide sterilization process and observing a color change. The reference notes that the device was capable of monitoring ethylene oxide sterilization (col. 6, lines 35-63).

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Larsson et al.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6-8, 11, 42, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al in view of US Patent 6,287,518 to Ignacio et al.

The disclosure of Larsson et al is described above. Larsson et al fails to disclose cellulose polymers for the sterilization indicator. Larsson et al also fails to disclose the particular cations, recited in claims 42, 44 and 47.

Ignacio et al teach devices for monitoring sterilization processes. The devices comprise an indicator and polymer. As polymers, Ignacio teaches cellulose materials, such as methyl cellulose. Ignacio et al teach that the polymers provide adequate binding of the indicator composition to a substrate. The polymers also influence the rate at which the sterilization chemical penetrates the indicator. It would have been obvious, to one of ordinary skill in the art to use cellulose materials as the polymer in Larsson et al for its ability to adhere the indicator composition to a substrate. In doing so, this would assure that the indicator composition remains in place during the testing.

With respect to the monovalent cations, Ignacio et al teach activators for pH indicators. As activators, the reference teaches alkali metal salts, such as magnesium halide and potassium halides. The reference teaches that activators react with the indicator to form an observable color change. It would have been obvious to one of ordinary skill in the art to substitute the

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magnesium halide of Larsson et al for the potassium halide taught by Ignacio et al because the reference teaches their equivalency in reacting with the indicator sufficiently enough to result in a detectable color change.

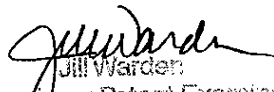
Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Larsson et al and Ignacio et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The Examiner is scheduled to relocate on December 17, 2003. After this date the Examiner may be reached at (571) 272-1156.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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December 15, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700